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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/701,303	11/28/2000	Akihiko Sano	0020-4771P	8796

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EXAMINER
JOYNES, ROBERT M

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 07/16/2002 10

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/701,303	Applicant(s) SANO ET AL.	
	Examiner Robert M. Joynes	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 April 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 8 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Receipt is acknowledged of applicants' Information Disclosure Statement filed on March 22, 2002 and Request for Reconsideration filed on April 29, 2002.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 6 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Cardinal (US 4601893). Cardinal teaches a multi-layer laminate core sheet that can contain one or more active agents (Col. 3, lines 15-36). The device is comprised or two or more core sheets fro controlled release of two or more active agents wherein the ends of said sheets are either exposed or unexposed (Col. 5, line 53 – Col. 6, line 10). The core sheets and film coating can be made from the same polymeric material; one suitable polymer is silicone rubber (Col. 6, lines 32-67). Each core sheet can be but need not be separated by an impermeable polymer film (Col. 6, lines 11-22). The device can have different release profiles at a zero order rate (Col. 8, line 67 – Col. 9, line 8). The sheets are then rolled to form a rod-like device for oral administration (Col. 11, line 55 – Col. 12, line 66; See also Figures 3 & 4). Therefore, when rolled, the rod-like device has multi-layer containing different drugs or different concentrations of drugs within the layer or layers. Instant claims 1-4, 6 and 8 are anticipated by the Cardinal reference.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 4, 5 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cardinal. The teachings of Cardinal are discussed above. Cardinal does not expressly teach that the device comprises layers containing the same drug at different concentrations or a device with two or more drugs in the same layer.

Cardinal does teach that two or more drugs can be present in the device and that the device can contain different release profiles as stated above. Example 4 of the Specification teaches various drugs and concentrations for each drug that can incorporated into the device (Col. 17 and 18). At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to prepare a rod-like device with multiple layers wherein two or more drugs are incorporated in the device one in each layer or two or more of the drugs in a single layer. It would also be obvious

to provide differing layer with different concentrations. Cardinal is suggestive of such devices when describing all the embodiments recited in the specification at Example 4. One of ordinary skill would be able to choose two different drugs with different concentrations to incorporate into the device.

One of ordinary skill in the art would have been motivated to incorporated two or more drugs in a single layer to minimize the size or thickness of the device (Col. 12, lines 30-66). One of ordinary skill in the art would be motivated to use different concentrations to provide varying release profiles of the drug over and extended period of time.

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Response to Arguments

Applicant's arguments with respect to claims 1-8 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Due to the new grounds of rejection, this action is deemed non-final.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert M. Joynes whose telephone number is (703) 308-8869. The examiner can normally be reached on Monday through Friday 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (703) 308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3592 for regular communications and (703) 305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Robert M. Joynes
Patent Examiner
Art Unit 1615
July 10, 2002

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
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